

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

Honorable Karen Williams
Magistrate Judge

Honorable Thomas Vanaskie
(Ret.),
Special Discovery Master

**[PROPOSED] ORDER
GRANTING MOTION TO
SEAL PURSUANT TO
L.CIV.R. 5.3(c)**

THIS MATTER having been brought before the Court by way of the Motion to Seal Pursuant to Local Civil Rule 5.3(c) (the “Motion to Seal”) filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. (“ZHP”), Princeton Pharmaceutical Inc. (“Princeton”), Huahai U.S. Inc. (“Huahai U.S.”), and Solco Healthcare U.S., LLC (“Solco,” and collectively with ZHP and Princeton, “the ZHP Parties”) on notice to liaison counsel for Plaintiffs; and the Court having considered the parties’ submissions and proposed sealed information, and the factors contained in Local Civil Rule 5.3(c)(2); and the Court having further found that the standards

set forth in Local Rule 5.3(c) have been met, the Court makes the following Findings of Fact and Conclusions of Law:

FINDINGS OF FACT

1. Through discovery in this case, the ZHP Parties have produced confidential information, the public disclosure of which would affect ZHP's legitimate business interests and competitive standing. To protect the confidentiality of information produced in discovery in this case, the parties negotiated and agreed to maintain the confidentiality of any materials produced pursuant to the Confidentiality and Protective Order (the "Protective Order"), entered by the Honorable Robert B. Kugler on June 26, 2019 ([ECF No. 139](#)).

2. The Protective Order permits the producing party to safeguard information by designating a document either "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION."

3. The Protective Order defines the type of information that warrants a confidentiality designation:

The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith

to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.

“RESTRICTED CONFIDENTIAL INFORMATION” means Documents that a Party has designated as “RESTRICTED CONFIDENTIAL” in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including proprietary manufacturing and production information (including formulation); business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm . . .

([Dkt. 139](#), ¶¶ 9(B), (M).)

4. The Protective Order also takes a pragmatic view of confidentiality designations given the size and scope of this litigation.

It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as “CONFIDENTIAL INFORMATION” in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions

(*Id.* ¶ [9\(B\)](#)).

5. This is particularly true where, as here, the ZHP Parties are competitors not only with the other manufacturer defendants in this MDL, but with companies

not included in this MDL, in a highly competitive market for generic pharmaceuticals. The Protective Order is designed to ensure that documents properly designated as either “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” are not subject to unfettered disclosure so as to protect the parties from the risk of significant competitive harm.

6. Pursuant to the Protective Order, a party may designate a document as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. *Id.* [¶¶ 22, 24](#).

7. The Protective Order further provides that any party wishing to file with the Court material designated as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” must file a Motion to Seal pursuant to Local Rule 5.3(c). 3. *Id.* [¶ 31](#).

8. Pursuant to the Protective Order, the ZHP Parties move to redact and seal a portion of Plaintiffs’ brief in opposition to the ZHP Parties’ motion for a protective order precluding the deposition of Baohua Chen ([ECF No. 1298](#)) (“Plaintiff’s Opposition Brief”), and Exhibit KK thereto.

9. Exhibit KK is an excerpt from the deposition transcript of Dr. Xiaodi Guo dated May 20, 2021. In the excerpt, Dr. Guo is asked by Plaintiffs’ attorney, David Hobbs, to testify in detail about the contents of an email thread from January

2010 concerning an email from Remonda Gergis, Vice President of Quality Assurance for Princeton, ZHP's U.S. subsidiary, FDA liaison and the ANDA holder for ZHP's finished dose products. This email thread was produced in this litigation and designated "RESTRICTED CONFIDENTIAL INFORMATION" by ZHP.

10. These emails, which are internal to ZHP and not intended for external dissemination, describe in detail the results of an internal audit of ZHP's finished dose manufacturing facility conducted by Ms. Gergis in January 2010. Information regarding the ZHP Parties' internal audits is highly confidential, and competitively sensitive information, and properly designated as "RESTRICTED CONFIDENTIAL" under the Protective Order.

11. The ZHP Parties believe in good faith that if the contents of these emails are disclosed through the information contained in Exhibit KK, and the reference to Exhibit KK in Plaintiffs' Opposition Brief, they will suffer significant competitive harm in the form of disclosure of their internal audit processes to their direct competitors, and that such disclosure would impede the ability of Princeton to conduct and provide ZHP with confidential and critical assessments of its manufacturing practices and processes in accordance with its own internal standards, consistent with its quality assurance obligations, without fear of public scrutiny, especially by its competitors.

12. Courts have recognized that the presumption of public access is not absolute and may be rebutted. *See In re Avandia Mktg., Sales Practices & Prods. Liability Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). The party seeking to overcome the presumption of access must show “that the interest in secrecy outweighs the presumption.” *Avandia*, 924 F.3d at 672 (3d Cir. 2019) (quoting *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). To do so, the movant must demonstrate “that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)); *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir. 1984)); *Pansy*, 23 F.3d at 787. The Court must then determine if the harm from the articulated injury outweighs the presumption of access. *Pa. Nat’l Mut. Casualty Ins. Grp. v. New Eng. Reins. Corp.*, — F. App’x —, 2020 WL 7663878, at *1 (3d Cir. Dec. 24, 2020).

13. Under Local Rule 5.3(c), the provisions of which a motion to redact and seal must satisfy, documents may be filed and maintained under seal upon a showing of good cause. *See* L. CIV. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv-1262, 2008 WL 834399, at *3 (D.N.J. Mar. 27, 2008). The moving party must show that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public

interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. *See* Local Rule 5.3(c)(3). This Court has discretion in balancing the factors for and against access to court documents. *See Pansy v. Stroudsburg*, 23 F. 3d 772, 791 (3rd Cir. 1994).

14. As set forth below, the ZHP Parties satisfy the criteria for sealing set forth in Local Rule 5.3(c).

A. The ZHP Parties' Legitimate Interest in Maintaining the Confidentiality of Exhibit KK and References Thereto

15. The ZHP Parties have a legitimate interest in maintaining the confidentiality of commercially sensitive business information, including its internal audit results, procedures, and methodology.

16. It is well-known that the pharmaceutical industry is a “highly competitive market where companies routinely attempt to discover a possible advantage over their competitors.” *See Public Citizen Health Research Grp. v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002); *see also United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165 GHK (SS), 2016 WL 6542729, at *4 (C.D. Cal. Mar. 14, 2016) (“In a field as competitive and technical as the pharmaceutical

industry, success or failure will turn in large measure on innovation”) (internal citation omitted).¹

17. In the pharmaceutical manufacturing context, courts have recognized the need to protect from disclosure internal audit reports, procedures, and methodology to protect a litigant’s standing in the marketplace. *See In re Incretin-Based Therapies Prods. Liability Litig.*, No. 13-md-2452, 2021 WL 873290, *2 (S.D. Cal. Mar. 9, 2021) (granting drug manufacturer’s omnibus motion to seal internal regulatory and safety analyses where “[d]efendants’ interest in safeguarding these competitive business materials overcomes the general presumption of public access”); *see also In re Cendant Corp.*, 260 F.3d 183, 192 (3d Cir. 2001) (granting motions to seal “confidential research, development, or commercial information’ to prevent harm to a litigant’s standing in the marketplace.”).

18. Disclosure of the ZHP Parties’ internal audits and analyses would be of economic value to many of the ZHP Parties’ competitors, including, but not limited to, those named as defendants in this MDL, because they reveal the processes the ZHP Parties developed to prepare for FDA inspections and comply with rigorous

¹ The U.S. Food and Drug Administration recognizes that clinical, safety and efficacy data constitute “confidential commercial information,” and are, therefore, exempt from FOIA disclosure requirements. *See* 39 Fed. Reg. 44602, 44634 (Dec. 24, 1974) (release of data upon request would allow “me-too” drugs to be marketed immediately); *see also* 21 C.F.R. § 314.430 (preventing disclosure by FDA of non-public safety, efficacy, and testing data).

FDA standards—information courts in the Third Circuit have held to be properly confidential. *See Supernus Pharms., Inc. v. Twi Pharms., Inc.*, No. 15-0369 (RMB/JS), 2017 WL 3671522 at *1-2 (D.N.J. Aug. 24, 2017) (finding defendants possessed a legitimate private interest in keeping commercially sensitive communications with the FDA concerning defendants' ANDA product); *Novartis Pharms. Corp. v. Mylan Pharms., Inc.*, No. 06-2885 (MLC), 2008 WL 11383884 at *1-2 (D.N.J. Oct. 31, 2008) (granting motion to seal documents, including confidential communications with the FDA, where Novartis had a legitimate business interest in preventing the disclosure of confidential and proprietary information, and where disclosure of such information would result in competitors gaining an unfair competitive advantage in the marketplace).

19. Furthermore, maintaining the confidentiality of this information is essential to the ZHP Parties' ability to undertake unfettered internal audits of its manufacturing facilities and make assessments, based on their own internal standards, to ensure adherence to current Good Manufacturing Practices (cGMP). *See Neorx Corp. v. Immunomedics Inc.*, No. 92-2853, 1993 WL 493880, at *2-3 (D.N.J. Sep. 30, 1993) (affirming an order protecting from disclosure drug manufacturer's good clinical practice audit reports on the grounds that they were subject to a "self-evaluative privilege," whereby a company's internal self-criticisms

or evaluations may be properly maintained as confidential to encourage unfettered internal criticism.).

B. If Exhibit KK Were Disclosed, ZHP Would Suffer a Clearly Defined and Serious Injury

20. The clearly defined and serious injury that would result should the proposed Order to seal not be entered is that the ZHP Parties would suffer significant competitive harm as a result of the disclosure of internal audit information to their competitors, many of whom are defendants in this MDL, and other competitors who are not but could access this information if it were made publicly available. Disclosing this information would compromise the integrity of future audits by causing future participants to be less candid in their remarks, or future auditors to be less frank in their assessments or recommendations out of fear that any statements would be publicized and misconstrued, even decades after the fact. Depriving the ZHP Parties of the ability to make open assessments of their manufacturing practices and processes against their own internal standards, would hamper the ZHP Parties' ability to self-correct or continually improve its manufacturing practices and processes, with an aim towards continuously ensuring the delivery of safe, effective, and affordable medications to patients.

C. There Is No Less Restrictive Alternative Available to Sealing Exhibit KK

21. There is no less restrictive alternative available other than to redact and seal Exhibit KK and the single paragraph of Plaintiffs' Opposition Brief that references it. The ZHP Parties have analyzed Exhibit KK to identify which information should be sealed, and have sought to redact only those portions of Exhibit KK that disclose the contents of the emails designated as "RESTRICTED CONFIDENTIAL."

D. There Is No Prior Order Sealing Exhibit KK

22. There is no prior order sealing Exhibit KK or Plaintiffs' Opposition Brief, or the underlying documents discussed therein in the pending action.

E. Plaintiffs' Objections to Sealing Exhibit KK

23. Plaintiffs have objected to the sealing request on the grounds that confidential treatment is not justified under the Protective Order in light of what they describe as a public health interest. *See Avandia*, 924 F.3d at 671 (identifying "various factors that courts may consider when determining whether good cause exists and, by extension, whether a protective order should issue," including, "whether confidentiality is being sought over information important to public health and safety.") But in *Avandia*, the Court advised that these factors were discretionary; not mandatory, and should be considered as part of a balancing test. *See id.* Plaintiffs have not articulated how the emails discussed in Exhibit KK even relate to, let alone

are important to public health and safety given that they describe an internal audit that occurred more than a decade ago. Nor have they articulated how this outweighs the ZHP Parties' interest in safeguarding its proprietary commercial information. Here, the ZHP Parties have detailed how the disclosure of their proprietary manufacturing, testing, and self-auditing information to the public and their direct competitors would impair their ability to compete in the generic drug marketplace.

24. Conversely, as outlined below, most of the *Avandia* factors weigh against disclosure of Exhibit KK. For example:

- Disclosure of information contained in the underlying emails would violate the privacy interests of the ZHP Parties' employees, including Ms. Gergis, who made her remarks to her superiors at ZHP without the expectation of public disclosure.
- The information contained in the underlying emails is now more than a decade out of date, and disclosure now fails to address any current concerns.
- Disclosure of information contained in the underlying emails to the ZHP Parties' fellow litigants would not promote fairness and efficacy—rather, because many of the ZHP Parties' fellow litigants in the MDL are manufacturer defendants and the ZHP Parties' direct competitors, disclosure would risk and may result in competitive harm to the ZHP Parties.
- The ZHP Parties are private companies, whose internal self-audit communications were not intended for public disclosure;

See Order Granting in Part and Denying in Part Motion to Seal dated May 24, 2021 (Vanaskie, J.) ([ECF No. 1269](#)) (citing *Avandia*, 924 F.3d at 670).

25. The Court, having considered this matter pursuant to Local Civil Rule 5.3(c), and the submissions in support of the Motion to Seal, finds that the ZHP Parties have satisfied their burden of establishing under Local Civil Rule 5.3(c) and applicable case law that Exhibit KK, and the paragraph of Plaintiffs' Opposition Brief referencing Exhibit KK, sought to be redacted and sealed by the ZHP Parties contains RESTRICTED CONFIDENTIAL information.

26. Pursuant to the foregoing Findings of Fact and Conclusions of Law, and for good cause shown:

IT IS on this _____ day of _____, 2021, hereby

ORDERED that the ZHP Parties' Motion to Seal is hereby **GRANTED**; and

IT IS FURTHER ORDERED that Exhibit KK, and the related portion of Plaintiffs' brief discussing Exhibit KK, shall remain sealed.

IT IS FURTHER ORDERED that a copy of this Order shall be served on all counsel of record within ____ days of Plaintiffs' liaison counsel's receipt of this Order.

Dated: _____

By the Court:

Hon. Thomas Vanaskie, (Ret.)
Special Discovery Master